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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/067,731	02/04/2002	Jeffrey Morse Holloway	71086	8128
22242	7590	05/19/2004		
FITCH EVEN TABIN AND FLANNERY 120 SOUTH LA SALLE STREET SUITE 1600 CHICAGO, IL 60603-3406				
			EXAMINER CHORBAJI, MONZER R	
			ART UNIT 1744	PAPER NUMBER

DATE MAILED: 05/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	<b>Application No.</b> 10/067,731	<b>Applicant(s)</b> HOLLOWAY ET AL.	
	<b>Examiner</b> MONZER R CHORBAJI	<b>Art Unit</b> 1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 14 January 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10-16 and 19-42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10-16 and 19-42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 May 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                    | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

**This non-final office action is in response to the amendment received on 01/14/2004**

#### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-2, 4-6, 16, 19-22, 26, 29, 35, 37-38, 40, and 42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In claim 1, line 6; applicant uses the term "per pulse". The original disclosure does not teach such a feature. The same applies to claims 4-5, 16, 19, 21-22, 26, 35, 37, 40, and 42.

In claim 2, lines 5-6; applicant added the following features: "wherein said method does not include the addition of a quenching agent, photoradiation sensitizer, or albumin". The original disclosure does not teach such a feature. The same applies to claims 6, 20, 22, 26, 29, 35, 38, and 40.

#### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1-8, 10-13, and 22-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Dwyer et al (U.S.P.N. 6,312,931) in view of Horowitz et al (U.S.P.N. 5,981,163).

With respect to claims 1, 5, 8, 22, 26, and 29, O'Dwyer et al teaches a method for inactivating microbes (col.3, lines 33-37) in a blood derived compounds (col.4, lines 5-6) including the following: illuminating with pulses of light (col.3, lines 35-38), a pulse

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duration of less than 100 ms (abstract, lines 12-13), wavelength range of 170 to 2600 nm (abstract, lines 14-15), a fluence greater than about  $0.001 \text{ j / cm}^2$  (col.4, lines 41-44), a fluence of about 0.05 to about  $15 \text{ j / cm}^2$  (col.4, lines 42-43), flowing blood derived compounds through a treatment chamber and illuminating while the compounds are flowing (col.7, lines 24-37), and a transmissive chamber to at least 1% of a light treatment (col.7, lines 26-32, col.9, lines 66-67, and col.10, lines 1-5 such that it is credible to believe that the treatment chamber must be transmissive to at least 1% of light in order to inactivate microbes in blood derived compounds). However, with respect to claims 1, 5, 8, 22, 26, and 29, O'Dwyer et al fails to teach the following: illuminating a platelet composition, decreasing platelet aggregation by not more than about 40%, and inactivating microbes in the platelet composition by at least about 2 logs. With respect to claims 1, 5, 8, 22, 26, and 29, Horowitz et al teaches the following: a method of irradiating microbes in a platelet composition (col.6, lines 27-33) at least about 2 logs (col.10, lines 9-11). Horowitz et al teaches that the platelet aggregation improved from about 70% to more than 90% of control levels, meaning that the decrease of platelet aggregation is not more than about 40%. Thus. It would have been obvious to one having ordinary skill in the art to modify the method of O'Dwyer et al to include a step of pulsing platelet composition in order to inactivate viruses in platelet concentrates (Horowitz et al, col.3, lines 50-55).

With respect to claims 2,4, 6, 10-12, 23, 25, 27, 30-33, O'Dwyer et al teaches the following: illuminating with pulses of light having wavelengths between 240 nm and about 280 nm (abstract, lines 14-15), a fluence of about 0.1 to about  $0.6 \text{ j / cm}^2$

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(abstract, lines 12-13), blood derived compounds is flowed through the treatment chamber at a constant flow rate (col.7, lines 24-32 such that in order to inactivate microbes it is credible to believe that the method of O'Dwyer et al is flowing blood compounds at a constant flow rate), it is known for UV light to be concentrated at wavelengths within a range of 200 to 300 nm (col.2, lines 13-17), and a pulse duration of less than 100 ms (abstract, lines 13-14).

With respect to claim 3, 7, 13, 24, 28, and 34, Horowitz et al teaches that any type of platelet concentrate can be illuminated (col.6, lines 29-30), and a fluence of 0.2 m/cm<sup>2</sup> (col.6, lines 58-59)

7. Claims 14-16, 19-21, 35-37, and 40-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Dwyer et al (U.S.P.N. 6,312,931) in view of Horowitz et al (U.S.P.N. 5,981,163) and further in view of Platz et al (U.S.P.N. 6,187,572).

With respect to claims 14, 19, 35, and 40, O'Dwyer et al fails to teach repeating the illumination of the platelet composition every 6 hours and not decreasing platelet aggregation by more than about 40%. However, with respect to claim 35, O'Dwyer et al increases the shelf life of blood components by illuminating them with BSPL. Horowitz et al teaches that the platelet aggregation improved from about 70% to more that 90% of control levels, meaning that the decrease of platelet aggregation is not more that about 40% but fails to teach repeating the illumination of the platelet composition every 6 hours. However, Platz et al teaches repeating the illumination every 2 minutes for a total time of 10 minutes (col.28, lines 65-67 and col.29, lines 1-3) and also illuminating continuously for 6 hours (col.35, lines 37-38). In addition, Platz et al teaches illuminating

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for 90 minutes to achieve a certain log viral reduction (col.35, lines 57-58). Thus. It would have been obvious to one having ordinary skill in the art to modify the method of O'Dwyer et al to include a step of repeating illumination every certain number of hours in order to achieve a desired value for the log reduction of viruses (Platz et al, col.35, lines 57-58).

With respect to claims 15-16, 20-21, 36-37, and 41-42, O'Dwyer et al teaches illuminating with pulses of light having wavelengths between 240 nm and about 280 nm (abstract, lines 14-15) and a fluence of about 0.1 to about 0.6 j / cm<sup>2</sup> (abstract, lines 12-13).

### ***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 38-39 are rejected under 35 U.S.C. 102(e) as being anticipated by O'Dwyer et al (U.S.P.N. 6,312,931).

With respect to claim 38, O'Dwyer et al discloses inactivating endogenous nucleic acid strands (col.5, lines 65-67 and col.6, lines 1-3) by illuminating an organism containing the nucleic acid strands (col.5, lines 65-67) with pulses of BSPL (col.5, lines 62-64).

With respect to claim 39, O'Dwyer et al teaches that the nucleic acid to be inactivated is endogenous and contained as part of a eukaryotic cell (col.5, lines 60-67).

The applied reference has a common inventor and a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

### ***Response to Arguments***

10. Applicant's arguments with respect to claims 1-8, 10-16, and 19-42 have been considered but are moot in view of the new ground(s) of rejection.

With respect to claims 1-8, 10-16, and 19-42, O'Dwyer et al teaches pulsing blood-derived isolates with BSPL having a pulse duration of less than 100 ms in order to inactivate pathogens

On page 14 of the response, applicant argues, "Claim 14 of the present application teaches repeating illumination every 6 hours and not continuous illumination for 6 hours as taught by Platz et al". In col. 28, lines 65-67 and col.29, lines 1-8, Platz et al teaches measuring the temperature of the fluid being illuminated in order to make sure that the suspension did not overheat such that each illumination period is 2 minutes. This means irradiating for 2 minutes, then stop to dilute and measure the



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temperature of the suspension then repeat for another 2 minutes for a total of 10 minutes.

On page 16 of the response, applicant argues, "None of the cited references teach the illumination of biological compositions without the addition of a quenching agent or chemical sensitizer or albumin". However, as indicated above the original disclosure does not teach such a limitation. Thus, it is considered new matter issues. In addition, Platz et al teaches illuminating without the addition of any chemical agent (example 2, col.29, lines 50-53).

### ***Conclusion***

11. The prior art made of record but not relied upon is considered pertinent to applicant's disclosure. Clark et al (U.S.P.N. 5,786,598) teaches using pulsing without the addition of any compound.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONZER R CHORBAJI whose telephone number is (571) 272-1271. The examiner can normally be reached on M-F 8:30-5:00.

13. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ROBERT J WARDEN can be reached on (571) 272-1281. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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14. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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